

REMARKS**Summary of the Amendments**

By the foregoing amendment, claim 1 has been amended, whereby claims 1 and 3-7 will remain pending. Of the pending claims, claim 1 is independent.

The amendment to the specification and claims is made herein without expressing agreement and/or acquiescence with the rejections of record, and is merely being made in an attempt to advance the present application to allowance. In particular, the amendment herein is made in accordance with language discussed with the Examiners during an October 5, 2009 interview (with a statement regarding the interview being presented below).

Moreover, as will discussed below, the specification and claims have been amended to even more precisely include literal language

Reconsideration of the rejections of record with allowance of the application is respectfully requested.

Statement of Interview

Applicants express appreciation for the courtesies extended by Supervisory Patent Examiner Frederick Krass and Examiner Lezah W Roberts during an October 5, 2009 interview with Applicants' representatives Arnold Turk and Mariko Matsukawa.

During the interview, Applicants' representatives pointed out that the literal English translation of the International application will be amended to more

precisely include "*Perilla frutescens var. crispa flutescen purpurea*" as compared to "*Perilla frutescen var. crispa*"; and to correct the spelling of "rosmarinic acid".

Applicants' showing of unexpected results was discussed in conjunction with Applicants' claimed subject matter. In particular, amendment of claim 1 was discussed to be directed to an agent for dissolving dental calculus, which comprises a composition comprising glycolic acid and an aqueous extract from *Perilla frutescens var. crispa flutescen purpurea* comprising polyphenols including rosmarinic acid, the polyphenols and the glycolic acid being present as a combination of active ingredients in an amount effective to achieve dissolving of dental calculus. The Examiners' attention was directed to Applicants' specification, such as at the paragraph beginning at the middle of page 5, regarding the disclosure of extracts and rosmarinic acid.

The Examiners were also advised it appears that the *Perilla frutescens var. crispa flutescen purpurea* product sold by Meiji Seika Kaisha, Ltd., as disclosed in Applicants' specification, such as at page 5, lines 24-25, and the Examples, includes 60% of dextrin, 35% of extracts from red prilla, and 5% citric acid, and that a major polyphenol contained in the product is rosmarinic acid – containing about 3.3% of rosmarinic acid and 8% of water.

Applicants' representative indicated that information regarding the Meiji Seika Kaisha, Ltd. product would be submitted with the response, and that a Supplemental Declaration Under 37 C.F.R. § 1.132 will be presented more precisely naming *Perilla frutescens var. crispa flutescen purpurea*.

The Examiner indicated that it appeared that claim 1, if amended as presented herein, is commensurate in scope with the unexpected showings, and should be allowable over the prior art of record subject to further search and consideration.

Request for Entry of Corrected Literal English Translation

Applicants are submitting on even date herewith a Petition Under 37 C.F.R. 1.181 for Entry of Corrected Literal English Translation of International Application and a Corrected Literal English Translation of International Application,

As noted in the Petition, during preparation of a response to the August 7, 2009 Final Office Action, Applicants noted that the term "*perilla frutescen var. crispa*" is a general term covering various homologous plants and includes "red shiso" (*perilla frutescens var. crispa flutescen purpurea*) as a typical species. In the Japanese language International Application, the term "赤しそ" (red shiso) is used to mean "*perilla frutescens var. crispa flutescen purpurea*" which is rich in rosmarinic acid as explained page 5, line 16 of the English language translation of the International application.

Moreover, it was additionally noted that the spelling of "rosmarinic acid" should be corrected in the English translation of the International application from "rosemarinic acid".

Accordingly, a Corrected Literal English Translation is being submitted with the Petition to even further ensure the accuracy of the literal English

translation of the International Application by submitting a corrected translation in which "*perilla frutescen var. crispa*" has been replaced with "*perilla frutescens var. crispa flutescen purpurea*" in each location in Applicants' originally filed literal English translation specification. Applicants submit that the amendment to the specification does not add new matter and has been made to present a more accurate translation.

Applicants also draw attention to copies of documents submitted with the Petition, i.e., a copy of a document labeled Exhibit A (2 pages printed) downloaded September 15, 2009 from the website http://en.wikipedia.org/wiki/Rosmarinic_acid showing information regarding rosmarinic acid; a copy of a document labeled Exhibit B (4 pages printed) downloaded September 15, 2009 from the website <http://www.shootgardening.co.uk/sitePlant.php?plantid=5287&name=perilla-frutescens-var-crispa> showing information regarding Curly perilla (*Perilla frutescens var. crispa*); and a copy of a document labeled Exhibit C (1 page printed) downloaded September 15, 2009 from the website http://en.wikipedia.org/wiki/File:Red_Shiso_-_Perilla_frutescens_var._crispa_f._purpurea.jpg showing information regarding Red Shiso – *Perilla frutescens var. crispa f. purpurea*.

Accordingly, entry of the Petition and the Corrected Literal English Translation of International Application are respectfully requested.

Response To Art-Based Rejections

The following rejections are set forth in the Office Action:

(a) Claims 1, 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over in Melman (US 2002/0156130) in view of Oriza (JP 2000-239136).

(b) Claims 3, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over in Melman (US 2002/0156130) in view of Oriza (JP 2000-239136), as applied to claims 1, 4 and 5, and further in view of Zhu (WO 01/17494) and Tagashira et al. (JP409295944).

Applicants again submit that for the reasons of record a *prima facie* cases of obviousness has not been established by any of the rejections of record; and that, even if for the sake of argument a *prima facie* case of obviousness has been established in any of the rejections, unexpected results associated with Applicants' claimed subject matter are further evidence of patentability of Applicants' claimed subject matter.

During the October 5, 2009 personal interview at the Patent and Trademark Office, the Examiners were reminded that a Declaration Under 37 C.F.R. 1.132 had been submitted on January 8, 2008, which shows the unexpected advantages associated with the recited combination of polyphenol and glycolic acid as compared to the individual use of polyphenol and glycol acid. It was noted that the Declaration establishes that as compared to examples using polyphenol or glycolic acid, i.e., Examples 3 and 18 of Applicants' originally filed application, respectively, an example using a combination of polyphenol and

glycolic acid achieves unexpected advantages. It was also pointed out that in Applicants' application and in the Declaration "*Perilla frutescen var. crispa*" should be "*Perilla frutescens var. crispa flutescen purpurea*", and that the translation will be corrected when filing the response, and that a Supplemental Declaration will be filed.

Accordingly, as noted above, a Petition and Corrected Literal English Translation of International Application are being filed on even date herewith, and a Supplemental Declaration Under 37 C.F.R. 1.132 is also being submitted. In particular, the Supplemental Declaration shows that in Example 3 wherein *Perilla frutescens var. crispa flutescen purpurea* polyphenol was used in the absence of inclusion of additional active ingredient, 50% weight of the dental calculus was dissolved after 105 minutes, and in Example 18 wherein glycolic acid was used in the absence of inclusion of additional active ingredient, 44% weight of the dental calculus was dissolved after 9 minutes. In contrast, Applicants note that when polyphenol and glycolic acid were utilized in combination, there is obtained a more rapid dissolving of the dental calculus, i.e., 50% weight of the dental calculus was dissolved after 6 minutes.

The Office Action agrees that the relative showings in the Declaration appear to be adequate to establish unexpected results; however, the Office Action contends that the claims are not commensurate in scope with the compositions of the Declaration. However, during the above-noted interview, the Examiners indicated that it appeared that claim 1, as amended herein, is commensurate in scope with the showings of the Declaration, which are presently included in the

Supplemental Declaration, and therefore the claims should be indicated to be allowable over the prior art of record.

While Applicants submit that the showing of unexpected results overcomes any *prima facie* case of obviousness, Applicants once again submit that a *prima facie* case of obviousness has not been established. In this regard, Applicants once again submit that the obviousness rejection based upon Melman in view of Oriza is without appropriate basis and does not establish a *prima facie* case of obviousness. Moreover, Applicants submit that even if for the sake of argument a *prima facie* case of obviousness is considered to be established, Applicants' showing of unexpected results, as noted above, overcomes any *prima facie* case of obviousness.

For the sake of brevity, and in view of the indication at the interview that the application appeared to be in condition for allowance upon presentation of the amended claim 1, Applicants are not repeating each of the arguments as previously submitted, but incorporate the arguments, including the arguments submitted April 30, 2009, as if set forth in full herein.

Additionally, so that the record is complete, Applicants are submitting herewith materials about the product of Meija Seika Kaisha, Ltd. disclosed in Applicants' application. Information about the amount of rosmarinic acid was obtained by Applicants from the supplier of the product of Meiji extract, i.e., Meiji Food Materia Co., Ltd (<http://www.meijifm.co.jp/english.html>), a member company of the Meiji Seika group, from which the product disclosed by our client was obtained. "Meiji Red-Shiso Polyphenol" is listed in the supplier's Internet

home page, with "Red-Shiso" meaning "*Perilla frutescens* var. *crispa flutescen purpurea*", and explanation of "Rosmarinic acid 3.3% or more" as the standard of the product "Meiji Red-Shiso Polyphenol". Our client also obtained "Report of analysis of materials" from Meiji Food Materia Co., Ltd., indicating that this product contains 35% of an extract from Red-Shiso (*Perilla frutescens* var. *crispa flutescen purpurea*) derived from China.

Attached herewith are copies of:

(1) a document (2 printed pages) downloaded from the website

<http://www.meijifm.co.jp/products/index.html> accompanied by an English translation of the marked portion;

(2) a document (1 printed page) downloaded from the website

http://www.meijifm.co.jp/products/newmat_item.html accompanied by an English translation of the marked portion; and

(3) a letter dated September 7, 2009 from Meiji Food Materia Co., Ltd. New Materials Division providing Ingredient Search Report on "Meiji Red-Shiso (*Perilla frutescens* var. *crispa flutescen purpurea*) Polyphenol of their company.

Accordingly, withdrawal of the rejections of record with the mailing of the Notices of Allowance and Allowability is respectfully requested.

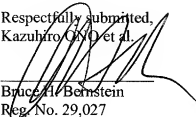
CONCLUSION

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the rejections of record, and allow each of the pending claims.

Applicants therefore respectfully request that an early indication of allowance of the application be indicated by the mailing of the Notices of Allowance and Allowability.

Should the Examiner have any questions regarding this application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,
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